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following chelation in children with autistic spectrum disorders in comparison to neurotypical children was most likely a consequence of biochemical deficit, possibly as a result of a pre-existing genetic condition, that caused children with autistic spectrum disorders to have a decreased ability to excrete mercury, resulting in their retention of potentially toxic levels of mercury. Independently, and in confirmation of the chelation study, researchers, including the *Chairman of the Chemistry Department of the University of Kentucky*, and other researchers, from the *Massachusetts Institute of Technology (MIT)*, including the *Director of the Nuclear Laboratory at MIT*, have evaluated mercury excretion in autistic children, and determined that had a significant decreased ability to excrete mercury in comparison to non-autistics.<sup>97</sup>

#### **Clinical Epidemiological Studies of Biochemical & Genomic Differences in Autistic Children**

Researchers from the *University of Arkansas* have examined cysteine and glutathione plasma levels in children with autistic disorders in comparison to matched neurotypical children.<sup>98</sup> It has been demonstrated that there statistically significant reductions in plasma cysteine (22% reduction) and glutathione (49% reduction) in children with autistic disorders in comparison to the matched neurotypical children. Both, cysteine and glutathione, possess a strong ability to bind mercury at the -SH (thiol) site of cysteine. Hence, a decrease in cysteine and glutathione availability would be expected to negatively affect the ability to bind mercury in vulnerable sites, particularly the brain, and may have relevance to the neurological dysfunction observed in childhood neurodevelopmental disorders.

In confirmation of the biochemical observations in autistic children, researchers have also analyzed genomic differences in autistic children in comparison to controls, and determined that there are statistically significant increased frequencies of single nucleotide polymorphisms (SNPs) for specific key functional enzymes within the glutathione synthesis pathway that would be expected to reduce the level of cysteine and glutathione present in autistic children.<sup>99</sup>

<sup>97</sup> Holmes AS, Blaxill MF, Haley BE. Reduced levels of mercury in first baby haircuts of autistic children. *Int J Toxicol* 2003;22:277-85.

Hu LW, Bernard JA, Che J. Neutron activation analysis of hair samples for the identification of autism. *Trans Am Nucl Soc* 2003;89.

<sup>98</sup> James SJ. Impaired transsulfuration and oxidative stress in autistic children: Improvement with targeted nutritional intervention. Fall DAN!™ 2003 Conference, Portland, Oregon, 3-5 October 2003.

James SJ. Increased oxidative stress and impaired methylation capacity in children with autism: metabolic biomarkers and genetic predisposition. Fall DAN!™ 2004 Conference, Los Angeles, CA, 1-3 October 2004, pgs. 143-159.

<sup>99</sup> Boris M, Goldblatt A, Galanko J, James SJ. Association of 5,10-Methylenetetrahydrofolate reductase (MTHFR) gene polymorphisms with autistic spectrum disorders. *J Am Phys Surg* (in press).

James SJ. Increased oxidative stress and impaired methylation capacity in children with autism: metabolic biomarkers and genetic predisposition. Fall DAN!™ 2003 Conference, Los Angeles, CA, 1-3 October 2004, pgs. 143-159.

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Independently, Westphal et al. have also examined the genomic differences in individuals sensitive to thimerosal in comparison to individuals not sensitive to thimerosal.<sup>100</sup> The researchers reported [emphasis added]:

*Thimerosal is an important preservative in vaccines and ophthalmologic preparations... There is evidence for the involvement of the glutathione system in the metabolism of thimerosal or its decomposition products (organomercury alkyl compounds). Thus detoxification by polymorphically expressed glutathione S-transferases such as GSTT1 and GSTM1 might have a protective effect against sensitization by these substances. To address this question, a case control study was conducted, including 91 Central European individuals with a positive patch-test reaction to thimerosal. This population was compared with 169 healthy controls and additionally with 114 individuals affected by an allergy against para-substituted aryl compounds. The latter population was included in order to test whether possible associations were due to substance-specific effects, or were a general feature connected with type IV immunological diseases. Homozygous deletions of GSTT1 and GSTM1 were determined by polymerase chain reaction. Glutathione S-transferase M1 deficiency was significantly more frequent among patients sensitized to thimerosal (65.9%, P = 0.013) compared with the healthy control group (49.1%) and the "para-compound" group (48%, P = 0.034). Glutathione S-transferase T1 deficiency in the thimerosal/mercury group (19.8%) was barely elevated versus healthy controls (16.0%) and the "para-compound" group (14.0%). The combined deletion (GSTT1-GSTM1-) was markedly more frequent among thimerosal-sensitized patients than in healthy controls (17.6% vs. 6.5%, P = 0.0093) and in the "para-compound" group (17.6% vs. 6.1%, P = 0.014), revealing a synergistic effect of these enzyme deficiencies (healthy controls vs. thimerosal GSTM1 negative individuals, OR 2.0 [CI 1.2-3.4], GSTT1-, OR 1.2 [CI 0.70-2.1], GSTM1:T1-, OR 3.1 [CI 1.4-6.5]). Since the glutathione-dependent system was repeatedly shown to be involved in the metabolism of thimerosal decomposition products, the observed association may be of functional relevance.*

#### Molecular Biology Observations & Animal Model Systems

Researchers from *Baylor College of Medicine* demonstrated that micromolar (parts-per-million – levels less than 4-times higher than children received from the routinely recommended childhood immunization schedule) concentrations of Thimerosal induced membrane and DNA damage, and initiated caspase-3 dependent apoptosis in human neurons and fibroblasts within hours following exposure.<sup>101</sup>

<sup>100</sup> Westphal GA, Schnuch A, Schulz TG, Reich K, Aberer W, Brasch J, Koch P, Wessbecker R, Sziliska C, Bauer A, Hallier E. Homozygous gene deletions of the glutathione S-transferases M1 and T1 are associated with thimerosal sensitization. *Int Arch Occup Environ Health* 2000;73:384-8.

<sup>101</sup> Baskin DS, Ngo H, Didenko VV. Thimerosal induces DNA breaks, caspase-3 activation, membrane damage, and cell death in cultured human neurons and fibroblasts. *Toxicol Sci* 2003;74:361-8.

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Researchers from the University of California, Irvine, including the Chief of the Division of Basic and Clinical Immunology, Department of Medicine at the University of California, Irvine, have examined the effects of Thimerosal on the biochemical and molecular steps of mitochondrial pathway of apoptosis in Jurkat T cells. The researchers determined that Thimerosal at nanomolar concentrations (**< 1 part-per-million**) induced apoptosis in T cells via a mitochondrial pathway by inducing oxidative stress and depletion of glutathione.<sup>102</sup>

Westphal et al. have evaluated the *in vitro* toxicity of thimerosal.<sup>103</sup> They reported [emphasis added]:

*Thimerosal is a widely used preservative in health care products, especially in vaccines. Due to possible adverse health effects, investigations on its metabolism and toxicity are urgently needed... Therefore, we reinvestigated thimerosal in the cytochalasin B block micronucleus test. Glutathione S-transferases were proposed to be involved in the detoxification of thimerosal or its decomposition products. Since the outcome of genotoxicity studies can be dependent on the metabolic competence of the cells used, we were additionally interested whether polymorphisms of glutathione S-transferases (GSTM1, GSTT1, or GSTP1) may influence the results of the micronucleus test with primary human lymphocytes. Blood samples of six healthy donors of different glutathione S-transferase genotypes were included in the study. At least two independent experiments were performed for each blood donor. Significant induction of micronuclei was seen at concentrations between 0.05-0.5 micro g/ml in 14 out of 16 experiments. Thus, genotoxic effects were seen even at concentrations which can occur at the injection site. Toxicity and toxicity-related elevation of micronuclei was seen at and above 0.6 micro g/ml thimerosal. Marked individual and intraindividual variations in the in vitro response to thimerosal among the different blood donors occurred. However, there was no association observed with any of the glutathione S-transferase polymorphism investigated. In conclusion, thimerosal is genotoxic in the cytochalasin B block micronucleus test with human lymphocytes. These data raise some concern on the widespread use of thimerosal.*

Researchers from the University of Arkansas and the Food and Drug Administration have examined ability of Thimerosal to damage neurons. They reported that the neurotoxicity of Thimerosal is associated with depletion of glutathione. The ethylmercury in Thimerosal binds to cysteine thiol (-SH) groups on intracellular proteins and inactivates their function. The cysteine-SH group of glutathione, binds mercury and protects essential proteins from functional inactivation. Glutathione is the major mechanism of

<sup>102</sup> Makani S, Gollapudi S, Yel L, Chiplunkar S, Gupta S. Biochemical and molecular basis of Thimerosal-induced apoptosis in T cells: a major role of mitochondrial pathway. *Genes Immun* 2002;3:270-8.

<sup>103</sup> Westphal GA, Asgari S, Schulz TG, Bunge J, Muller M, Hallier E. Thimerosal induces micronuclei in the cytochalasin B block micronucleus test with human lymphocytes. *Arch Toxicol* 2003;77:50-5.

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mercury excretion, and individuals with genetic deficiencies in glutathione synthesis will be less able to excrete mercury and will be more sensitive to its adverse effects.<sup>104</sup>

Jin et al., from the Seoul National University College of Medicine, have examined the way in which Thimerosal affects pain receptors.<sup>105</sup> The authors reported:

*TRPV1, a receptor for capsaicin, plays a key role in mediating thermal and inflammatory pain. Because the modulation of ion channels by the cellular redox state is a significant determinant of channel function, we investigated the effects of sulfhydryl modification on the activity of TRPV1. Thimerosal, which oxidizes sulfhydryls, blocked the capsaicin-activated inward current (I<sub>cap</sub>) in cultured sensory neurons, in a reversible and dose-dependent manner, which was prevented by the co-application of the reducing agent, dithiothreitol. Among the three cysteine residues of TRPV1 that are exposed to the extracellular space, the oxidation-induced effect of thimerosal on I<sub>cap</sub> was blocked only by a point mutation at Cys621. These results suggest that the modification of an extracellular thiol group can alter the activity of TRPV1. Consequently, we propose that such a modulation of the redox state might regulate the physiological activity of TRPV1.*

Other researchers from Northeastern University, Tufts University, Johns Hopkins University, and the University of Nebraska have reported that methylation events play a critical role in the ability of growth factors to promote normal development. Neurodevelopmental toxins, such as ethanol and heavy metals, interrupt growth factor signaling, raising the possibility that they might exert adverse effects on methylation. The researchers determined that insulin-like growth factor-1 (IGF-1)- and dopamine-stimulated methionine synthase (MS) activity and folate-dependent methylation of phospholipids in SH-SY5Y human neuroblastoma cells, via a PI3-kinase- and MAP-kinase-dependent mechanism. The stimulation of this pathway increased DNA methylation, while its inhibition increased methylation-sensitive gene expression. It was determined that mercury from Thimerosal inhibited both IGF-1- and dopamine-stimulated methylation significantly at sub-nanomolar (< 0.001 parts-per-million -- levels considerably less than children receive from Thimerosal-containing childhood vaccines) concentrations and eliminated MS activity. The researchers concluded that these findings provide a molecular mechanism for how increased use of Thimerosal-containing vaccines may have contributed to the observed increase in autism and Attention-Deficit-Hyperactivity-Disorders (ADHD).<sup>106</sup> In addition, researchers have

<sup>104</sup> James SJ, Slikker W, Melnyk S, New E, Pogribna M, Jernigan S. Thimerosal neurotoxicity is associated with glutathione depletion: protection with glutathione precursors. *Neurotoxicology* (in press).  
James SJ. Increased oxidative stress and impaired methylation capacity in children with autism: metabolic biomarkers and genetic predisposition. Fall DAN!™ 2003 Conference, Los Angeles, CA, 1-3 October 2004, pgs. 143-159.

<sup>105</sup> Jin Y, Kim DK, Khil LY, Oh U, Kim J, Kwak J. Thimerosal decreases TRPV1 activity by oxidation of extracellular sulfhydryl residues. *Neurosci Lett* 2004;369:250-5.

<sup>106</sup> Waly M, Olteanu H, Banerjee R, Choi SW, Mason JB, Parker BS, Sukumar S, Shim S, Sharma A, Benzecri JM, Power-Charnitsky VA, Deth RC. Activation of methionine synthase by insulin-like growth

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followed-up this previous work and shown that folate-dependent, phospholipid methylation in the lymphoblasts of autistic children were significantly in a dose-response manner more sensitive to Thimerosal than in unaffected siblings.<sup>107</sup>

Leong et al. have examined the effects of nanomolar (i.e. < 1 part-per-million) concentrations of mercury ions (i.e. the final break down product of Thimerosal in the human body) on neuron damage.<sup>108</sup> They have reported:

*However the precise site and mode of action of Hg ions remain illusive. Therefore, the present study examined whether Hg [mercury] ions could affect membrane dynamics of neurite growth cone morphology and behavior. Since tubulin is a highly conserved cytoskeletal protein in both vertebrates and invertebrates, we hypothesized that growth cones from animal species could be highly susceptible to Hg ions. To test this possibility, the identified, large Pedal A (PeA) neurons from the central ring ganglia of the snail Lymnaea stagnalis were cultured for 48 h in 2 ml brain conditioned medium (CM). Following neurite outgrowth, metal chloride solution (2 microl) of Hg, Al [aluminum], Pb [lead], Cd [cadmium], or Mn [manganese] (10<sup>-7</sup> M) was pressure applied directly onto individual growth cones. Time-lapse images with inverted microscopy were acquired prior to, during, and after the metal ion exposure. We demonstrate that Hg ions markedly disrupted membrane structure and linear growth rates of imaged neurites in 77% of all nerve growth cones. When growth cones were stained with antibodies specific for both tubulin and actin, it was the tubulin/microtubule structure that disintegrated following Hg exposure. Moreover, some denuded neurites were also observed to form neurofibrillary aggregates. In contrast, growth cone exposure to other metal ions did not effect growth cone morphology, nor was their motility rate compromised. To determine the growth suppressive effects of Hg ions on neuronal sprouting, cells were cultured either in the presence or absence of Hg ions. We found that in the presence of Hg ions, neuronal somata failed to sprout, whereas other metallic ions did not effect growth patterns of cultured PeA cells. We conclude that this visual evidence and previous biochemical data strongly implicate Hg as a potential etiological factor in neurodegeneration.*

Consistent with the findings by Leong et al., other researchers have observed similar *in vitro* effects of Thimerosal on brain tubulin assembly.<sup>109</sup>

Stajich et al. from Mercer University have evaluated blood mercury levels pre- and post-immunization in infants vaccinated with thimerosal-containing vaccines. The researchers reported:

factor-I and dopamine: a target for neurodevelopmental toxins and Thimerosal, Mol Psychiatry 2004;9:358-70.

<sup>107</sup> Deth RC, Waly M. How genetic risks combine with Thimerosal to inhibit methionine synthase and cause autism. Fall DAN!™ 2004 Conference, Los Angeles, California, 1-3 October 2004, pgs. 161-174.

<sup>108</sup> Leong CC, Syed NI, Lorscheider FL. Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following *in vitro* exposure to mercury. Neuroreport 2001;12:733-7.

<sup>109</sup> Brunner M, Alberini S, Wurgler FE. Effects of 10 known or suspected spindle poisons in the *in vitro* porcine brain tubulin assembly assay. Mutagenesis 1991;6:65-70.

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*Thimerosal, a derivative of mercury, is used as a preservative in hepatitis B vaccines. We measured total mercury levels before and after the administration of this vaccine in 15 preterm and 5 term infants. Comparison of pre- and post-vaccination mercury levels showed a significant [ $P < 0.05$ ] increase in both preterm and term infants after vaccination.<sup>110</sup>*

A Researcher from the Food and Drug Administration has confirmed that Thimerosal crosses the blood-brain barrier and placental barriers and results in appreciable mercury content in tissues including the brain.<sup>111</sup>

Wright et al. from the US Department of Agriculture evaluated retention of mercury in tissues of cattle and sheep oral doses of an ethylmercury-containing compound [i.e. Ceresan M]. The researchers reported:

*A mercurial fungicide, formerly used, Ceresan M (ethyl mercury p-toluene sulfonamide), was given in oral doses at 15 mg/Kg to cattle for 7 or 12 days and to sheep for 4 or 7 days [3.2% of the total compound is mercury - 480 micrograms of mercury/Kg]. Residues of mercury in hair, blood and tissues [i.e. including, the brain] were determined by atomic absorption spectrophotometry for 20 weeks after dosing had ceased. Residues of mercury increased in the hair of cattle to a maximum point and then began to decrease. Residues in brain and muscle of both cattle and sheep were lower initially than in liver and kidney and then decreased during the 20-week postexposure. Mercury persisted in tissues of cattle throughout the study.<sup>112</sup>*

Recently, researchers from the University of Washington have recently reported the half-life of mercury in the brain of infant primates was approximately 28 days following injection of solutions containing vaccine comparable concentrations of Thimerosal, and other researchers have shown that methylmercury and Thimerosal when injected into mice similarly distributed in the organs.<sup>113</sup>

Mukai has reported on an animal model of ethylmercury-cysteine induced encephalopathy. Mukai published:

*Mice injected intraperitoneally with EMC (Ethyl Mercury-S-Cysteine) labeled with tritium showed the typical neurologic symptoms of mercury poisoning. Administration of EMC in a concentration of 0.3 mg/0.5 ml. saline per day for at*

<sup>110</sup> Slajich GV, Lopez GP, Harry SW, Saxon WR. Iatrogenic exposure to mercury after hepatitis B vaccination in preterm infants. J Pediatr 2000;136:679-81.

<sup>111</sup> Slikker W. Developmental neurotoxicology of therapeutics: survey of novel recent findings. Neurotoxicology 2000;21:250.

<sup>112</sup> Wright FC, Palmer JS, Riner JC. Retention of mercury in tissues of cattle and sheep given oral doses of a mercurial fungicide, Ceresan M. J Agric Food Chem 1973;21:614-5.

<sup>113</sup> Plaintiff's Exhibit Misc - 1975.

Institute of Medicine (US). Immunization Safety Review: Vaccines and Autism. Washington, DC: National Academy Press, 2004.



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*least eight days was a prerequisite for significant accretion of EMC in the central nervous system. The extent and distribution of cell damage were highly predictable, and selective necrosis of the small granular neurons in the koniocortex, and neostriatum was a constant finding. Autoradiographic study has suggested that the astroglial cell compartment plays a role in conveying the mercury complex into neurons.<sup>114</sup>*

Researchers from Columbia University have reported that the developing brain of autoimmune prone mice is uniquely susceptible to the neurotoxic effects of Thimerosal.<sup>115</sup> They administered Thimerosal to mice mimicking the United States' routine childhood immunization schedule. The researchers demonstrated a genetically-susceptible autoimmune prone mouse strain developed symptoms similar to autistic disorders. Symptoms included growth delay, reduced locomotion, exaggerated response to novelty, increased brain size, decreased numbers of Purkinje cells, significant abnormalities in brain architecture, affecting areas subserving emotion and cognition, and densely packed hyperchromic hippocampal neurons with altered glutamate receptors and transporters.

Researchers, including ones from the University of Rochester, have also developed a mouse model to evaluate the neurotoxic effects of short-chained alkyl mercury exposure on different sexes.<sup>116</sup> Two-day-old mice were administered short chained alkyl mercury at 4 mg of mercury /Kg body weight (low dose), 8 mg of mercury /Kg body weight (high dose), or no mercury. Animals were sacrificed 24 hours later, and matched sections of brain were prepared. The total number of mitotic figures in the external granule layer of the cerebellar cortex were recorded and classified as early (prophase and metaphase) or late (anaphase and telophase). Mercury concentrations in the brain for both males and females were 2.7 µg mercury /g at the 8 mg mercury / Kg dose and 1.8 µg mercury /g at the 4 mg mercury /Kg dose. The authors determined that at the high dose, male and female mice had similarly reduced percentages of late mitotic figures compared with controls. At the lower dose, female mice were significantly much less affected in their percentages of late mitotic figures compared with male mice. The researchers determined that males are considerably more sensitive than females to the neurotoxic effects of mercury. It has observed in some human fetal/infant population exposures to low dose short-chained alkyl mercury that males were more sensitive than females to psychomotor retardation.<sup>117</sup> As noted, neurodevelopmental disorders in the United States are significantly more prevalent in males than females.

<sup>114</sup> Mukai N. An experimental study of alkylmercurial encephalopathy. Acta Neuropathol (Berl). 1972;22:102-9.

<sup>115</sup> Hornig M, Chian D, Lipkin WI. Neurotoxic effects of postnatal Thimerosal are mouse strain dependent. Mol Psychiatry 2004;9:833-45.

<sup>116</sup> Clarkson TW, Nordberg FJ, Sager PR. Reproductive and developmental toxicity of metals. Scand J Work Environ Health 1985;11:145-54.

Sager PR, Aschner M, Rodier PM. Persistent differential alterations in developing cerebellar cortex of male and female mice after methylmercury exposure. Brain Res 1984;314:1-11.

<sup>117</sup> Clarkson TW, Nordberg FJ, Sager PR. Reproductive and developmental toxicity of metals. Scand J Work Environ Health 1985;11:145-54.

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### Other Areas of Significant Concern

In 1999, Dr. Thomas Verstraeten of the CDC began a study of Thimerosal in the CDC's VSD that reviewed the medical records of hundreds of thousands of children. The VSD is a massive database that tracks the medical records of hundreds of thousands of patients belonging to seven major health maintenance organizations. The findings of Dr. Verstraeten from his study of the VSD set off a fierce debate within the Federal health agencies when they were internally released in June 2000. Enough concern was generated that a closed-private conference of medical experts was assembled at the Simpsonwood Retreat Center near Atlanta, Georgia. Among those in attendance included representatives from: CDC, FDA, Aventis Pasteur, Wyeth, Merck, SmithKline Beecham, North American Vaccine. The following are some statements that were recorded as part of the official transcript [emphasis added]:

Dr. Bernier: Page 113: *We have asked you to keep this information confidential...So we are asking people who have done a great job protecting this information up until now, to continue to do that until the time of the ACIP meeting...That would help all of us to use the machinery that we have in place for considering these data and for arriving at policy recommendations.*

Dr. Verstraeten: Page 31: *Now it turns out that other people also thought that this study was not the right thing to do, so what I will present to you is the study that nobody thought we should do.*

Dr. Verstraeten: Page 40: *...we have found statistically significant relationships between the exposures and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay, which has its own specific ICD-9 code. Exposure at three months of age, Tics. Exposure at six months of age, an attention deficit disorder. Exposure at one, three and six months of age, language and speech delays which are two separate ICD-9 codes. Exposure at one, three and six months of age, the entire category of neurodevelopmental delays, which includes all of these plus a number of other disorders [i.e. including autism].*

Dr. Johnston: Page 198: *This association leads me to favor a recommendation that infants up to two years old not be immunized with Thimerosal containing vaccines if suitable alternative preparations are available...My gut feeling? It worries me enough. I forgive this personal comment, but I got called out at eight o'clock for an emergency call and my daughter-in-law delivered a son by C-Section. Our first male in the line of the next generation, and I do not want that grandson to get a Thimerosal containing vaccine until we know better what is going on. It will probably take a long time. In the meantime, and I know there are*

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Grandjean P, Weihe P, White RF, Debes F. Cognitive performance of children prenatally exposed to "safe" levels of methylmercury. Environ Res 1998;77:165-72.



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*probably implications for this internationally, but in the meantime I think I want that grandson to only be given Thimerosal-free vaccines.*

Dr. Weil: Page 207: *The number of dose related relationships are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant. The positive relationships are those that one might expect from the Faeroe Islands studies. They are also related to those data we do have on experimental animal data and similar to the neurodevelopmental tox data on other substances, so that I think you can't accept that this is out of the ordinary. It isn't out of the ordinary.*

Dr. Brent: Page 229: *The medical legal findings in this study, causal or not, are horrendous...So we are in a bad position from the standpoint of defending any lawsuits if they were initiated and I am concerned.*

Dr. Clements: Page 247: *I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which way the boat should go at all. And I really want to risk offending everyone in the room by saying that perhaps this study should not have been done at all, because the outcome of it could have, to some extent, been predicted, and we have all reached this point now where we are left hanging...But nonetheless, we know from many experiences in history that the pure scientist has done research because of pure science. But that pure science has resulted in splitting the atom or some other process which is completely beyond the power of the scientists who did the research to control it. And what we have here is people who have, for every best reason in the world, pursued a direction of research. But there is now the point at which the research results have to be handled, and even if this committee decides that there is no association and that information gets out, the work that has been done and through the freedom of information that will be taken by others and will be used in ways beyond the control of this group. And I am very concerned about that as I suspect it is already too late to do anything regardless of any professional body and what they say...*<sup>118</sup>

In November 2003, Verstraeten et al. finally published the study, but the early findings of a statistical association between Thimerosal and neurodevelopmental disorders were no longer present.<sup>119</sup> Dr. Verstraeten took to the unprecedented step following the publication of his paper to write a paper clarifying the results of his study. He stated that the researchers initially found a significant relationship between Thimerosal-containing childhood vaccines and some types of neurodevelopmental disorders, but upon further examination of a different dataset did not find a consistent effect, and that his study was

<sup>118</sup> Simpsonwood Meeting Transcript, June 7-8, 2000 in Norcross, Georgia. Obtained under by SafeMinds.

<sup>119</sup> Verstraeten T, Davis RL, DeStefano F, Lien TA, Rhodes PH, Black SB et al. Safety of Thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases. Pediatrics 2003;112:1039-48.

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neutral (i.e. could neither accept nor reject a causal relationship) regarding the relationship between Thimerosal and neurodevelopmental disorders.<sup>120</sup>

A report prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform of the United States' House of Representatives, concluded in 2003 following a three-year investigation [emphasis added]:

*Manufacturers of vaccines and Thimerosal (an ethylmercury compound used in vaccines), have never conducted adequate testing on the safety of Thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on Thimerosal and ethylmercury compounds... To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC's rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations... The Food and Drug Administration's (FDA) mission is to 'promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.' However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, 'at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of risk when its potential benefit is great-especially for products used to treat serious, life-threatening conditions. This argument-that known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to Thimerosal in vaccines-is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from Thimerosal was theoretical, that no proof of harm existed. However, the Committee, upon a thorough review of the scientific literature and internal documents from government and industry, did find evidence that Thimerosal did pose a risk. Thimerosal used as a preservative in vaccines is likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected Thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is*

<sup>120</sup> Verstraeten T. Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline. *Pediatrics* 2004;113:932.

*indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry.<sup>121</sup>*

The US Office of Special Counsel (OSC), an independent federal agency, has issued a letter to Congress on May 20, 2004 stating [emphasis added]:

*I have recently received hundreds of disclosures from private citizens alleging a widespread danger to the public health, specifically to infants and toddlers, caused by childhood vaccines which include Thimerosal, a mercury-containing preservative... I hasten to add, however, that based on the publicly available information, as discussed briefly below, it appears there may be sufficient evidence to find a substantial likelihood of a substantial and specific danger to public health caused by the use of Thimerosal/mercury in vaccines because of its inherent toxicity... The disclosures allege that Thimerosal/mercury is still present in childhood vaccines, contrary to statements made by HHS agencies, HHS Office of Investigations and the American Academy of Pediatrics. According to the information provided, vaccines containing 25 micrograms of mercury and carrying expiration dates of 2005, continue to be produced and administered. In addition, the disclosures allege, among other things, that some datasets showing a relationship between Thimerosal/mercury and neurological disorders no longer exist, that independent researchers have been arbitrarily denied access to the Centers for Disease Control and Prevention (CDC) databases, and that government-sponsored studies have not assessed the genetic vulnerabilities of subpopulations. Due to their heightened concern that additional datasets may be destroyed, these citizens urge the immediate safeguarding of the Vaccine Safety Datalink database, and other relevant CDC information, so that critical data are not lost. The disclosures also allege that the CDC and the Food and Drug Administration colluded with pharmaceutical companies at a conference in Norcross, Georgia, in June 2000, to prevent the release of a study which showed a statistical correlation between Thimerosal/mercury exposure through pediatric vaccines and neurological disorders, including autism, Attention-Deficit/Hyperactivity Disorder, stuttering, tics, and speech and language delays. Instead of releasing the data presented at the conference, the author of the study, Dr. Thomas Verstraeten, later published a different version of the study in the November 2003 issue of Pediatrics, which did not show a statistical correlation. No explanation has been provided for this discrepancy. Finally, the disclosures allege that there is an increasing body of clinical evidence on the connection of Thimerosal/mercury exposure to neurological disorders which is being ignored by government public health agencies... I believe that these allegations raise serious continuing concerns about the administration of the nation's vaccine program and the government's possibly inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines. The allegations also present troubling information regarding children's cumulative exposure to mercury and the connection of that exposure*

<sup>121</sup> Subcommittee on Human Rights and Wellness, Government Reform Committee, Mercury in Medicine Report, Washington, DC: Congressional Record, May 21, 2003:F1011-30.

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*to the increase in neurological disorders such as autism and autism-related conditions among children in the US.<sup>122</sup>*

The Office of Inspector General of the United States Department of Health and Human Services has written [emphasis added]:

*This letter is in response to your April 3, 2004 correspondence, which arrived at our office from Mr. Kenneth M. Donohue, acting in his capacity as Chairman of the Investigations Committee, President's Council on Integrity and Efficiency (PCIE). In his letter to this office, Mr. Donohue expressed concern over your allegation that Thimerosal is being used 'in order to increase the manufacturer's profit margins.' Such an allegation goes to perceived wrongdoing, and in that capacity, Mr. Donohue requested that this office provide a second review and take whatever action we deem appropriate. Upon review of the correspondence you provided to the PCIE, in conjunction with further research into the matter, we have determined that your above allegation represents a potential conflict-of-interest issue which may be criminal in nature and therefore falls within the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Investigations' (OI) authority to investigate.<sup>123</sup>*

On July 7, 1999 the American Academy of Pediatrics and the United States Public Health Service issued a joint calling on vaccine manufacturers to make a clear commitment to reduce as expeditiously as possible, the mercury content of their vaccines.<sup>124</sup> Despite such strong statements, Thimerosal presently remains in non-trace amounts (> 1 microgram of ethylmercury per dose) in many vaccines administered to children, including: Diphtheria-Tetanus (DT) vaccine, meningitis vaccine, Tetanus toxoid adsorbed vaccine, Japanese Encephalitis virus vaccine, Tetanus toxoid vaccine, influenza vaccine, and Tetanus-diphtheria (Td) vaccine. In addition, beginning this year (2004), influenza vaccine has been added to the routine childhood immunization schedule, so that children will receive three influenza vaccines during the first 18 months of life. Many of the formulations of influenza vaccine are still prepared with non-trace amounts of Thimerosal (12.5 or 25 micrograms of ethylmercury per dose), and the CDC will state no preference for use of Thimerosal-free influenza vaccine.<sup>125</sup> Hence, **Thimerosal is now being reintroduced into the routine childhood immunization schedule.**

<sup>122</sup> United States Office of Special Counsel, Special Counsel Scott Bloch's Letter to Congress, May 20, 2004.

<sup>123</sup> Deputy Inspector General for Investigations, Health and Human Services Michael Little to Reverend Lisa Sykes, July 19, 2003.

<sup>124</sup> Subcommittee on Human Rights and Wellness, Government Reform Committee, Mercury in Medicine Report, Washington, DC: Congressional Record, May 21, 2003:E1011-30.

<sup>125</sup> <http://www.aapf.org/x7666.xml>

Myron Levin, U.S. Won't Alert Parents, Doctors on Mercury in Flu Shots for Kids, LA Times - Home Edition, April 2, 2004, pg A1.

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In response to the continued presence of Thimerosal and the toxicity of Thimerosal in many childhood vaccines, individual states have now stepped into the FDA/CDC's role, and taken it upon themselves to ban Thimerosal from childhood vaccines.

The state of Iowa on May 14, 2004 (SF 2209) became the first state in the nation to ban the administration of Thimerosal-containing vaccines to children under the age of eight beginning on January 1, 2006.

On September 28, 2004 (AB 2943), California became the second state in the nation banning administration of Thimerosal-containing vaccines to children under the age of three and to pregnant women beginning on July 1, 2006. In actual debate on the bill within the California Legislature, it was stated:

*According to the author's office, this bill is intended to respond to growing concern that Thimerosal, a preservative containing approximately 50 percent ethyl mercury, could be contributing to increasing rates of neurodevelopment disorders, including autism, in children... This bill is meant to be a precautionary measure that would reduce infants' and children's overall exposure to mercury during critical developmental years. The author's office points out that the bill is timely because the federal Centers for Disease Control and Prevention (CDC) recommends that in 2005, all children ages six months to two years receive the flu vaccine, even though many of the pediatric doses will contain Thimerosal... Mercury is used in household and commercial products, as well as industrial processes, because it is liquid at room temperature, combines easily with other metals, and expands and contracts evenly with temperature changes. Mercury is an element that does not break down. It is a persistent and toxic pollutant that bio-accumulates in the environment and in the food chain and in the human body. There is no dispute within the scientific and medical communities concerning the serious ecological and health effects related to mercury. Mercury is a widely recognized toxin that can damage the central nervous system, kidneys and liver, at very low levels of exposure. Nervous system disorders include impaired vision, speech, hearing, and coordination. Mercury is especially hazardous to pregnant women and children, causing such problems as birth defects and learning disabilities. A National Academy of Sciences study published in 2000 estimated that annually 60,000 infants in the United States face increased risk of brain damage because of pregnant mothers' elevated exposures to mercury. In California, there is a special concern regarding the accumulation of methylmercury in the tissues of fish that can be consumed and result in damaging health effects. While it is known that mercury, on its own, as a heavy metal, is a toxin, combined with other chemicals or metals into different mercuric compounds, mercury may be more or less toxic to the human body depending on how the compounds are metabolized. Additionally, the impact of a compound on infants and children may differ from the effects on adults... Preservatives are used by drug companies to prevent the growth of bacteria and fungi in vaccines, preventing potentially life-threatening contamination by harmful microbes. Thimerosal is a preservative that has been used in the United States since the*

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1930's. It contains 50 percent ethyl mercury. In recent years, drug manufacturers have developed new products with alternatives or without preservatives that can be used as substitutes for many of the vaccinations available today. In 2001, the Institute of Medicine's (IOM) Immunization Safety Review Committee convened a meeting to review selected issues related to immunization safety. The IOM believed that the effort to remove Thimerosal from vaccines was "a prudent measure in support of the public health goal to reduce mercury exposure of infants and children as much as possible." The Committee also urged that "full consideration be given to removing Thimerosal from any biological product to which infants, children and pregnant women are exposed." According to the U.S. Food and Drug Administration (FDA), "As a precautionary measure, the Public Health Service (including the FDA, the National Institutes of Health (NIH), the CDC, Health Resources and Services Administration (HRSA) and the American Academy of Pediatrics) issued two Joint Statements, urging vaccine manufacturers to reduce or eliminate Thimerosal in vaccines as soon as possible (CDC 1999) and (CDC 2000)." Since 1999, Thimerosal has been removed from most of the vaccines routinely recommended for infants and children. It is still used in injectable influenza vaccine, though Thimerosal-free flu vaccine is expected to be available this year. In recent years, several studies have been conducted to look at a possible link between Thimerosal and neurodevelopmental disorders, such as autism, including the following: 1. In its report of 2001, IOM concluded that the evidence is inadequate to either accept or reject a causal relationship between Thimerosal exposure from childhood vaccines and neurodevelopmental disorders. 2. A 2003 report published by the Journal of American Physicians and Surgeons, conducted by Drs. Mark Geier and David Geier, asserts strong epidemiological evidence for a link between mercury exposure from Thimerosal-containing childhood vaccines and neurodevelopment disorders. 3. IOM released a report in May, 2004, reputing this and other studies, stating that the hypotheses regarding how the measles-mumps-rubella (MMR) vaccine and Thimerosal could trigger autism lack supporting evidence and are only theoretical, and that the MMR vaccine and the mercury based vaccine preservative Thimerosal are not associated with autism. 4. A study done by the University of Columbia, released June 8, 2004, states that the mercury preservative used in some vaccines can cause behavioral abnormalities in newborn mice characteristic of autism, but only in mice with specific genetic susceptibility.<sup>126</sup>

Many other states are in the process of considering similar bills to ban Thimerosal from vaccines. In addition, a bi-partisan bill (HR 4169) has been introduced into the United States' House of Representatives to ban Thimerosal from all vaccines administered in the United States.

Also, the Coalition for Mercury-free Drugs (CoMeD) filed on July 30, 2004 a Citizen Petition [FDA Dockets. 2004P-0349] with the FDA requesting the Secretary of Health and Human Services or the Acting Commissioner of Food and Drugs, as appropriate, to.

<sup>126</sup> <http://www.assembly.ca.gov/acs/acsframeset2text.htm>



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"1. IMMEDIATELY issue an order barring the administering of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than "trace" (more than 0.5 micrograms per dose) levels of mercury to pregnant women and children under the age of 36 months, on the grounds that higher levels are now a *proven* health hazard to "susceptible" fetuses, newborns and young children. 2. Suspend the approval or licensing of any FDA-regulated product that contains Thimerosal or any other mercury-based compounds as a preservative, or adjuvant, in the final formulation unless the total level of said compounds is *not more than* 0.5 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, not more than 0.5 micrograms of mercury per day, on the grounds that so doing will reduce the risks of adverse reactions in susceptible children under the authority conferred upon you by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. Section 300aa-10 et seq., under 42 U.S.C. Section 300aa-27(a)(2) for vaccines and, *for other drugs*, the general "public safety" authority granted in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Chapter 9). 3. Issue a Class I or, *failing that*, a Class II recall of all batches of multi-dose vaccines that contain a Thimerosal preservative level of more than .001% on the grounds that: a. All such multi-dose vaccine formulations are now a proven health hazard to susceptible individuals of all ages and b. Therefore, a recall will reduce the risk of adverse reactions that, *under the authority conferred upon you by the National Childhood Vaccine Injury Act of 1986*, you are directed to minimize, and 4. *To protect public health and safety*, issue orders: a. banning vaccines, and other drugs, containing more than 0.5 microgram of mercury per dose of product from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after 1 January 2006, and b. Requiring, *after 1 January 2006*, the recall and destruction of ALL: i. Vaccines remaining in commerce that contain more than 0.5 micrograms of mercury per dose, and, ii. Other drug products remaining in commerce that contain more than 1.0 micrograms of mercury per mL (or g) of drug, *unless the manufacturer thereof can prove that the mercury-based compound in said vaccine or other drug product causes no adverse neurological health outcomes in any group or subgroup of susceptible individuals, including, but not limited to, males, fetuses, newborns, children, and adolescents.*"<sup>127</sup>

Beyond the United States, the British Government recently announced that it was going to immediately remove Thimerosal from its childhood vaccinations amid fears that Thimerosal was linked to childhood autism.<sup>128</sup> Other European countries such as Denmark and Sweden, among others have previously banned Thimerosal-containing vaccines.

### Conclusion

Therefore, notwithstanding the recent conclusions of the National Academy of Sciences' Institute of Medicine that there is no relationship between autism and Thimerosal, and that no further scientific researcher should be undertaken to evaluate the

<sup>127</sup> FDA Dockets. 2004P-0349. Action on Products Containing Added Mercury.

<http://www.fda.gov/ohrt/dockets/dqulvs/04/aug04/08XN04/08X0404.htm>

<sup>128</sup> Autism Scrapped Over Autism Fears. BBC News - UK Edition, August 7, 2004.

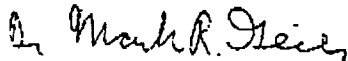
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relationship between autism and Thimerosal<sup>129</sup>, if a certain segment of the population has a decreased ability to excrete mercury, as has been demonstrated in children with neurodevelopmental disorders, there can be little doubt that mercury concentrations once administered to children as part of the routine childhood vaccination schedule resulted in a significant number of children developing neurodevelopmental disorders. This is especially true, and will result in a population epidemic, when there is a sudden shift in the amount of mercury administered, as occurred in the United States when the amount of mercury administered to children approximately tripled as part of the routine childhood immunization schedule in the first six months of life (i.e. from 75 micrograms of mercury generated as a result of three DTP immunizations beginning mercury exposure at 2 months of age in the mid-1980s to 187.5 micrograms from three DTP/DTaP, three Hib, and three hepatitis B immunizations beginning mercury exposure on the day of birth by the late-1990s), since the gene pool will contain many susceptible individuals that under previous environmental conditions would have been normal, but under the new environmental conditions are unable to thrive.

Based upon the foregoing, it is my opinion that the manufacturers were negligent in the use of thimerosal as preservative without warning consumers of the hazardous potential. In addition, products that contained thimerosal were unreasonably dangerous because its hazards are greater than an ordinary consumer would expect. Given the manufacturers knowledge and the manufacturers lack of reaction to that knowledge, this demonstrates deliberate indifference to the health and safety of others.



Mark R. Geier, M.D., Ph.D.

<sup>129</sup> Institute of Medicine (I&S). Immunization Safety Review: Vaccines and Autism. Washington, DC: National Academy Press, 2004.

**Cases Non-DPT**

Date	Case	Deposition/Trial	Attorney
09/27/2004	Valasquez v. United States Civil Action No. DKC-03-2142	Deposition	U.S. Department of Justice District of Maryland Northern Division 101 West Lombard St. Baltimore, MD 21201 Tarra DeShields
09/21/2004	Willie Brown	VCA Hearing	Tom Gallagher 822 Shore Road Somers Point, NJ 08244
10/08/2003	Shelly T. Buynum et al. In Circuit Court For Baltimore County Case No. 03-C-003171	Deposition	Charles E. McClain, Sr., Esquire 3100 Kitchie Road, Suite A Forestville, MD 20747
07/10/03	Eric Jefferies	Deposition - Hepatitis B	Clifford Shoemaker
07/7-8/2003	Richelle Pafford	VCA Hearing	Robert Moxley Gage & Moxley
05/20/2003	Issac v St. Mary's Hospital of Huntington, Inc. Civil Action No. 00-C-774 Circuit Court of Kanawha County, West Virginia	Trial - Medical Malpractice	Michael J. Del Giudice Ciccarello, Del Giudice & LaFon 1219 Va. St. E. Suite 100 Charleston, WV 25301
04/14/2003	Eric Jefferies v HHS 99-570V Special Master French	VCA Hearing— Hepatitis B	Clifford Shoemaker
04/10/2003	Veronika Lewis v Michael Reese Hospital Foundation et al. In the Circuit Court of Cook Count, Illinois No. 99 L 2766	Deposition II CVS	Weitz & Luxenberg 180 Maden Lane New York, NY 10038 Ellen Relkin
03/20/2003	Dixon v. HHS 01-0605V Special Master French	VCA Hearing - MMR/Autism	Miracle, Pruzan, Pruzan & Baker Suite 1550 1000 Second Avenue Seattle, WA 98104
02/14/2003	Issac v St. Mary's Hospital of Huntington, Inc. et al Civil Action No. 00-C-774 Circuit Court of Kanawha County, West Virginia	Deposition Medical Malpractice	Ciccarello, Del Giudice & LaFon Suite 100 1219 Virginia Street East Charleston, WV 25301 Michael Del Giudice
09/20/2002	Veronika Lewis v Michael Reese Hospital Foundation et al. In the Circuit Court of Cook Count, Illinois No. 99 L 2766	Deposition CVS	Weitz & Luxenberg 180 Maden Lane New York, NY 10038 Ellen Relkin
02/08/2002	Loutzenhiser et al., v the UT Southwestern Medical Center, et al. No. 94-1295h In The District Court of Dallas County, Texas	Deposition CVS	Thomas Bleakley 21 Kercheval Ave. Suite 232 Grosse Pointe Farms, Michigan 48236 (313) 640-9900
01/11/2002	Bradley Eidmann v Evanston Hospital Corporation and Scott N. MacGregor D.O. Circuit Court of Cook County No. 97 L 16287	Trial CVS	Thomas Bleakley 21 Kercheval Ave. Suite 232 Grosse Pointe Farms, Michigan 48236 (313) 640-9900

11-10-68

01/08/2002	Bradley Eidmann v Evanston Hospital Corporation and Scott N. MacGregor D.O. Circuit Court of Cook County No. 97 L 16287	Deposition CVS	Thomas Bleakley 21 Kercheval Ave. Suite 232 Grosse Pointe Farms, Michigan 48236 (313) 640-9900
12/11/2001	Williams v Alan Cadkin, M.D., et al. In the Circuit Court of Cook County, Illinois No. 99 L 9355	Deposition CVS	Thomas Bleakley 21 Kercheval Ave. Suite 232 Grosse Pointe Farms, Michigan 48236 (313) 640-9900
12/06/2001	Hailey vs HHS Vaccine Compensation Act	VCA Hearing Tetanus	Tom Gallagher
02/09/2001	Bradley Eidmann v Evanston Hospital Corporation and Scott N. MacGregor D.O. Circuit Court of Cook County No. 97 L 16287	Deposition CVS	Goldberg & Goldberg 33 North Dearborn Street
01/24/2000	Platt vs HHS Vaccine Compensation Act	VCA Rubella	Shoemaker
03/05/99	Sarah Kemats vs Howard O. Grundy, et al., State of Illinois Court of Cook 91 L 13537	Deposition CVS	Thomas Bleakley 21 Kercheval Ave. Suite 232 Grosse Pointe Farms, Michigan 48236 (313) 640-9900
02/12/99	Horowitz	Deposition CVS	Shainwald Law Offices 20 Exchange Place 45 <sup>th</sup> Floor New York, N.Y. 10007
08/25/98	Superior Court of N.J Chancery Division-Family Part Court of Hunterdon Docket No. FN-10-3-96 vs Helen & William Carey	Trail Shaken Baby Syndrome	Schenck, Price, Smith & King 10 Washington Street, P.O. Box 905 Morristown, N.J. 07963
03/20/98	Shaw vs Yu United States District Court for the District of Maryland Case No. WMN-94-2820	Deposition Amniocentesis not performed Downs baby	Shaw & Brown, P.A. 102 West Pa. Ave. Towson, MD 21204 Neal Brown (410) 823-9400
12/18/97	Emily Mateo vs Michael Reese Hospital & Medical Center, An Illinois Corp, Laurence Burd, M.D., Cook Urological, Inc. 93 L 6243	Deposition CVS	Bleakley & McKeen One Kennedy Square, Suite 1800 Detroit, MD 48226
12/04/97	Janice M. Maxfield & Charles E. Maxfield vs George Sun, The University of Chicago & Daniel A. Rightmire In the Circuit Court for the Seventh Judicial Circuit of Illinois, Sangamon County	Deposition CF	Talbert & Associates 630 East Broadway Alton, Illinois
04/04/97	Denise Striggles, et al vs National Health Laboratories, Inc. et al.	Deposition	Klores & Cardaro 915 15 <sup>th</sup> Street, N.W. Washington, D.C. 20005
05/02/96	Adria Palinsky vs Hutzel Hospital, Johnson, Evans and Reproductive Genetics	Deposition	Thomas Bleakley One Kennedy Square Suite 1800 Detroit, MD 482-7
03/26/96	Ann Kimberland vs Genetics & IVF Institute, Inc. et al.	Deposition	Charles Sickels 4010 University Drive

12/19/95	Lisa Withrow et al. vs Ujjal Sandhu et al. Civil No. 93-C4871 Circuit Court of Kanawah Court, WV	Deposition	Fairfax, VA 22030 David Skeen 411 D Street South Charleston, WV 25303
11/18/95	Hudak vs Filkins	Deposition	Joseph Hudak P.O. Box 23423 Fourth Avenue Station Pittsburgh, PA 15222
07/13/95	Hammond vs Merck Sharp and Dohme Case No. 94-30349-LAC US District Court Northern District of Florida Pensacola Division	Deposition Rubella	Samuel Bearman 18 North Palafox Street Pensacola, FL 32501
06/05/95	Platt vs HHS	VCA Hearing Rubella	Clifford Shoemaker
01/05/93	Sherry Terry	Deposition Auto Accident	David High 227 Second Avenue, N. Nashville, Tenn. 37201

FROM: JONATHAN L. SMITH--GEORGE

NOV 10 8 2004 17:04 ST. 17:03 11.03-11720

Vaccine Cases  
Updated February 11, 2003

Chikasuye V Connaught	6/85	deposition	McDowell & Colantoni
Corbine v Lederle	7/85	deposition	McDowell & Colantoni
Spizer v Lilly	10/22/85	deposition	McDowell & Colantoni
Yankovick v Lederle	11/5/85	deposition	McDowell & Colantoni
Dunn v Lederle	6/6/86	deposition	Casey & Ecton
Tyler White v Wyeth	2/12/86	deposition	McDowell & Colantoni
Tyler White v Wyeth	3/5/86	trial	McDowell & Colantoni
In the Court of Common Pleas			
State of Ohio, County of Cuyahoga			
Hodges v Wyeth	8/9/86	dep Part 1	McDowell & Colantoni
Hodges v Wyeth	9/16/86	dep Part 2	McDowell & Colantoni
Goodwin v Wyeth	10/1/86	deposition	McDowell & Colantoni
Hensley v Lederle	11/18/86	dep Pt 1	McDowell & Colantoni
Abbott v Lederle	12/2/86	deposition	McDowell & Colantoni
Ventimiglia v Moffitt (Wyeth)	12/19/86	deposition	McDowell & Colantoni
Finchem v Wyeth	1/7/87	deposition	Denner & Benjoya
Mobley v Lederle	2/11/87	dep-Pt 1	Denner & Benjoya
Mobley v Lederle	3/24/87	dep-Pt 2	Denner & Benjoya
Mobley v Lederle	3/25/87	dep-Pt 3	Denner & Benjoya
Leuzinger v Berke (Wyeth)	3/26/87	deposition	Warshafsky
LeMar v Lederle & (Connaught)	5/28/87	dep-Pt 1	Thomason, Hendrix et al
Dye/Watson v Furlong	7/15/87	deposition	McDowell & Colantoni
Hensley v Lederle	7/30/87	dep-Pt 2	McDowell & Colantoni
Graham v Wych	8/6/87	deposition	Michaud, Hutton & Bradshaw
Cooper v Wyeth	8/20/87	deposition	McDowell & Colantoni
Graham v Wyeth	8/26-28/87	trial	Michaud, Chaudry et al.
Lester v Wyeth	9/9/87	deposition	Dano Law Firm
Shaw v Troendle (Wyeth)	10/8/87	deposition	Berger & Montague
Rothwell v Connaught	11/30/87	trial	Dunlop & Associates
Cavallo v Wyeth	12/23/87	deposition	Warshafsky
Circuit Court of Milwaukee County - Civil Division Milwaukee, Wisconsin Case No. 716-507			
Norris v Wyeth	2/11/88	deposition	Margol Fryefield & Pennington
Kroboth v Lederle	2/19/88	deposition	McDowell & Colantoni



FROM: JOHN T. H. SMITH--GEORGE

INCL: NOV 8 2004 17:34 ST. 17:33 NO. 6341723636

Talley v Wyeth	2/24-25/88	deposition	Merritt, Rooney & Hayden
Cunningham v Lederle	3/3/88	deposition	McDowell & Colantoni
LaCombe/Brossuad			
v Lederle, Wyeth et al.	3/30/88	deposition	McDowell & Colantoni
Kelly v Parke-Davis	4/5-6/88	deposition	Strom, Buller & Cooke
Starr v Wyeth et al.	6/16/88	deposition	Peters, Fowler & Inslee
Price v Wyeth et al.	6/23/88	deposition	Clifford Shoemaker
Bovey v Parke-Davis	6/28/88	deposition	Strom, Buller & Cooke
In the Superior Court of The State of California			
County of Solano No. 84993			
Simpson, v Hussaini			
Wyeth, Lederle et al.	6/30/88	deposition	McDowell & Colantoni
McLean v Wyeth et al.	7/27/88	deposition	The McMath Law Firm
Souza v Alviso et al.	8/2/88	deposition	The Boccardo Law Firm
King v Lederle	8/11/88	deposition	Michaud & Hutton & Bradshaw
Hardaway	8/17/88	deposition	Aaron Levine
In the United States District Court			
for the Middle District of Tennessee			
Nashville Division CA. No. 3-87-0355			
Rogers v Wyeth	9/2/88	deposition	Hunt and Wilson
Jepsen v Wyeth	9/7/88	deposition	Kersten & McKinnon
Collins v Lederle	9/8/88	deposition	Von Erdsmanndorff
McLean v Wyeth et al.	9/20-21/88	deposition	The McMath Law Firm
Bovey v Park Davis	9/22/88	trial	Strom, Buller & Cooke
Osborne v U.S.A. & Connaught	10/11/88	deposition 1	Lembhard Howell
United States District Court			
Northeastern Division of North Dakota at Grand Forks			
Civil No. A2-86-160			
Fox v Canmann	10/18/88	deposition	McDowell & Colantoni
Johnson v Lederle	10/19/88	deposition	Meares, Morton & Meares
DiLeo v Wyeth	12/20/88	deposition	Ozzard, Wharton et al.
Superior Court of New Jersey			
Law Division, Middlesex County No. W-011580-86			
Meizinski v Wyeth	12/22/88	deposition	Zeff and Zeff & Materna
Frank Miller v Wyeth	1/10/89	deposition	McDowell & Colantoni
Nay v Wyeth et al.	1/12/89	deposition	McDowell & Colantoni
Superior Court of NJ			
Law Division, MERCER County			
Docket Number AM-1120-87-T1			
Hill v Lederle	1/17/89	deposition	Hunt and Wilson
Higham v Connaught	1/26/89	deposition	McDowell & Colantoni
Osborne v Connaught	2/10/89	deposition 2	Lembhard Howell
Lim v Connaught	2/14/89	deposition	Hullverson & Hullverson
Gatts v Lederle et al.	3/16/89	deposition	Hunt and Wilson

PROSECUTOR GENERAL'S OFFICE - GEORGE

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Greco v Lederle	3/21/88	deposition	Michaud, Hutton & Bradshaw
Fowler v Lederle	3/27/89	deposition	The McMath Law Firm
Rowsey v Connaught	3/30/89	deposition	McDowell & Colantoni
Hussey v Merrell			
Dow et.al.	4/5/89	deposition I	George W. Beals
Richardson v Lederle	4/6/89	deposition	Barnett & Ross
Stumpf	4/13/89	deposition	Zeff, Zeff & Materna
Hussey v Merrell Dow et al.	4/18/89	deposition	George W. Beals
Dow et al.			
Lim v Connaught	5/23/89	deposition	Hullverson & Hullverson
Joseph Davis	6/14/89	VCA	Clifford Shoemaker
Mabie v Wyeth et al.	6/22/89	deposition	Zeff Zeff & Materna
Scholl v Connaught	6/26/89	deposition	Denver & Dodd
Bailey	7/7/89	VCA	Schlictman, Conway, Crowely & Hugo
Behnke v Lederle	7/6/89	deposition (case No. 23101)	McDowell and Colantoni
State of Ohio			
County of Fulton			
Court of Common Pleas			
Lewis v Wyeth	7/13/89	deposition	Michaud, Hutton & Bradshaw
Steinfeld v Wyeth	7/18/89	deposition	Webb, Burton Carlson & Pederson
Ciotoli	7/25/89	VCA	McDowell & Colantoni
Kline	8/8/89	VCA	McDowell & Colantoni
Pusateri	9/8/89	VCA	McDowell & Colantoni
Donnelly	9/14/89	VCA	McDowell & Colantoni
Ioanescu	9/19/89	VCA	McDowell & Colantoni
Jackson v Lederle	9/20/89	deposition	McDowell & Colantoni
McGinty v Wyeth	9/21/89	deposition	George W. Beals
Monteverdi	9/30/89	VCA	McDowell & Colantoni
Boyd v Connaught	10/5/89	deposition	John G. Phillips & Assoc
State of Illinois			
County of Cook			
In the Circuit Court of Cook County, Illinois			
County Department, Law Division			
Siegfried	10/13/89	VCA	McDowell & Colantoni
Carlson	10/19/89	VCA	McDowell & Colantoni
Pollard	10/24/89	VCA	McDowell & Colantoni
Massing	10/24/89	VCA	Cloon & Bennett
Gunnells	10/24/89	VCA	Cloon & Bennett
Gowan	11/14/89	VCA	McDowell & Colantoni
Alger	11/15/89	VCA	Clifford J. Shoemaker
Kosten	11/22/89	deposition	Webb, Burton, Carlson et al.
Nuzzo	11/30/89	VCA	McDowell & Colantoni
Anderson v Lederle	12/5/89	deposition	Merkel & Cocke

FROM: JONATHAN A. SMITH--GEORGE

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Thomas v Lederle	1/12/90	deposition	Meares & Morton
Scherer v N St. Paul	1/24/90	deposition	Hunt & Wilson
Coleman v Kanawha	2/13/90	deposition	Gregory Elliott
Culbertson v Wyeth	2/27/90	deposition	McDowell & Colantoni
Tefoya	2/27/90	VCA	McDowell & Colantoni
Mitchell V Harris	03/01/90	deposition	O'Quinn & Kerensky
Vincent v Connaught	03/22/90	deposition	Hullverson & Hullverson
Berning v HHS	04/05/90	VCA	McDowell & Colantoni
LeJuene v Wyeth	04/10/90	deposition	Susman Godfrey
Wood v Lederle	04/12/90	deposition	O'Quinn, Kerensky
Essex	04/17/90	VCA	Michaud, Hutton & Bradshaw
Tucker v HHS	05/08/90	VCA	Carroll, Germain & Tobbe
Miller v Belka & Wyeth	05/09/90	deposition	Webb, Burton, Carlson et al.
Chronister v HHS	05/22/90	VCA	Adams, Day, Whitfield,
			Ramey and Burns
Lehmann v HHS	06/08/90	VCA	Webb, Burton, Carlson et al.
Hineline/Snowden			
v Connaught	06/15/90	deposition	Warshafsky, Rotter et.al
Barbee v Connaught	07/27/90	deposition	Hare, Wynn, Newell & Newton
Waddell III	09/25/90	VCA	Hanover, Walsh, et al.
Beck v HHS	10/02/90	VCA	Killion, Brooks & Schell
Raines v HHS	10/30/90	VCA	Meares & Morton
Overgard v HHS	11/01/90	VCA (MMR Case)	Gage & Moxley
Alien v HHS	11/08/90	VCA	Kirland, Barfield etc.
Coffelt v HHS	11/08/90	VCA	Gage & Moxley
Sumrall v HHS	11/20/90	VCA	Webb, Burton, Carlson et al.
McCutcheon v HHS	11/27/90	VCA	McDowell & Colantoni
Dempsey v Lederle	11/28/90	deposition	Webb, Burton, Carlson et al.
Thomas v American			
Cyanamid Company	12/6-11/90	trial	Meares & Morton
Mills v HHS	01/9/91	VCA	Weller, Whellus & Green
Johnson v HHS	01/25/91	VCA	Reams, Vollmer, et al.
Richardson v HHS	01/30/91	VCA	Hunt & Wilson
McClendon v HHS	01/31/91	VCA	Thomason, Hendrix et al.
DiLeo v HHS	01/31/91	VCA	Ozzard, Wharton, Rizzolo et al.
Summar v HHS	02/01/91	VCA	Thomason, Hendrix et al.
Maley V HHS	02/14/91	VCA	Gage & Moxley
Chapman V HHS	02/28/91	VCA	McDowell & Colantoni
Ponder V HHS	03/05/91	VCA	McMath
Zinko V HHS	03/12/91	VCA	Michaud, Hutton & Bradshaw
McDermott V HHS	03/19/91	VCA	Michaud, Hutton & Bradshaw
Long V HHS	03/28/91	VCA	McDowell & Colantoni
O'Connor V HHS	04/04/91	VCA	Gage & Moxley
Clark	04/23/91	Deposition	Joseph R. Neal

FROM: JON-THOMAS, SMITH-GEORGE

MONITOR # 2004 17135 ST. 17133 NO. 8341703366

Adkins V HHS	05/15/91	VCA	Schlictman, Conway, Crowley & Hugo
Graham	06/05/91	Deposition	Warshafsky, Rotter et al.
Walz V HHS	09/24/91	VCA	Gage & Moxley
Massing	10/10/91	Deposition	Cloon, Bennett, Ronan & Viveros
Gonzales V HHS	10/17/91	VCA	Peters, Fowler & Inslee
Thomas V HHS	10/30/91	VCA	Susman Godfrey
Sowdon V HHS	11/06/91	VCA	Andrew Dodd
Welsh V Lederle	11/19/91	Deposition	Poissant & Nichols
Cucuras V HHS	11/22/91	VCA	Gage & Moxley
Jones V Lederle	12/05/91	Trial	Glaser, Shandell & Blitz
Yeoman V HHS	12/17/91	VCA	Beezley
Phillips V HHS	01/10/92	VCA	Gage & Moxley
Aldridge V HHS	01/14/92	VCA	Thomason, Hendrix
Jensen V HHS	01/30/92	VCA	Williams, Trine, Greenstein & Griffith
Ormechea V HHS	02/07/92	VCA	Williams, Trine, Greenstein & Griffith
Maines V HHS	02/25/92	VCA	Thomas Gallagher
Jones V Wyeth	03/11/92	Deposition	McMath
Rabon V HHS	03/31/92	VCA	Joseph Neal
Pease V American Cyanamid Co.	04/03/92	Deposition	Janet & Strausberg
United States District Court for the District of Maryland Civil No. JFM-91-1654			
Einsphar V HHS	04/28/92	VCA	Gage & Moxley
Jepsen V. Wyeth	05/12/92	Deposition	Warshafsky, Rotter et al.
Snowdon V Connaught	07/27/92	Deposition	Michaud, Hutton & Bradshaw
Marascalco V HHS	08/10/92	VCA	Thomason, Hendrix et al.
Estep V HHS	08/14/92	VCA	Webb, Pederson et al.
Souza V Marsh			
McLenna, Inc.	12/03/92	Deposition	Boccardo Law Firm
Haim V HHS	05/07/93	VCA	Webb, Pedersen & Webb
Wolf V HHS	11/08/93	VCA	Boniello, Anton, Conti & Boniello
Randall V Lederle	11/30/93	Deposition	Warshafsky, Rotter et al.
Rutledge V HHS	12/13/93	VCA	Deborah Temples
Eng V HHS	12/15/93	VCA	David High
Keane V Lederle	12/17/93	Deposition	Joseph Matranga
Lacy V HHS	04/28/94	VCA	Boyd McDowell
Ponder V Connaught	08/04/94	Deposition	Sid McMath
Kopicki V Nicklas	08/12/94	Deposition	Motherway & Glenn
Johnson V HHS	09/21/94	VCA	Robert Moxley
Ponder V Connaught	10/11/94	Deposition Part 2	Sid McMath

FROM JONATHAN L. SMITH--GEORGE

RECEIVED 8 2004 17:38 ST. 17:38 NO. 8341723638

Nagy V HHS	11/02/94	VCA	Dobreff & Dobreff
Miller V Connaught	12/01/94	Deposition	Warshafsky, Rotter et al.
Epstein V HHS	04/11/95	VCA	Marilyn Rigmaiden
Thelen V Wyeth	06/02/95	Deposition	Webb, Pedersen & Webb
Platt V HHS	06/05/95	VCA	Shoemaker
Hughes V HHS	06/21/95	VCA	Mr. Ronan
Misenko V HHS	07/31/95	VCA	Becker & Mishkind
Reynolds V Connaught	09/12/95	Deposition	Hunt & Wilson
Lamb V HHS	09/21/95	VCA	Richard Oare
James V HHS	12/07/95	VCA	Caldwell
Braccio V Haddonfield			
Pediatrics, et al.	06/18/96	Deposition	Charles Lutz
Cox V HHS	11/26/96	VCA	Conrad Kindsfather
Elsener V HHS	12/12/96	VCA	William Pauzauskie
Jackson V HHS	04/29/97	VCA	O'Quinn & Laminack
Lucas V HHS	07/08/97	VCA	The Berean Law Group
Miles V Connaught	08/01/97	Deposition	Hugo
Horner V HHS	08/19/97	VCA	Stapleton
Jenkins V HHS	10/14/97	VCA	Mr. Shoemaker
O'Keefe V HHS	11/04/97	VCA	Mr. Gallagher
Connell V HHS	09/24/98	VCA	Mr. Gallagher
Salmond V HHS	11/12/98	VCA	Webb
Flippo V Skiowski &			
American Cyanamid Co.	12/15/98	Deposition	William C. Walker, Jr.
Oetting V HHS	02/10/99	VCA	Oyler & Pauzauskie
Lewis V HHS	04/28/99	VCA	Shoemaker/Horn
Mack V Lederle	07/15/99	Deposition	Hugo/Pollack
Raj V HHS	11/03/2000	VCA	Shoemaker/Horn
Watson V Connaught	04/13/2001	Deposition	Merritt
Watson V Connaught	04/24/2001	Deposition II	Merritt
Guzman V HHS	11/12/2002	Deposition	James Pagliuca

**CURRICULUM VITAE**

**Name** Mark Robin Geier

**Address** 14 Redgate Court  
Silver Spring, MD 20905

**Date of Birth** May 3, 1948

**Place of Birth** Washington, D.C.

**Marital Status** Married (Anne Watson Geier)  
Son - David (born 10/05/80)

**Education**

1970	B.S. George Washington University Washington, D.C.
1970-1971	Graduate Student Department of Human Genetics and Development, Columbia University, N.Y.C., N.Y.
1973	Ph.D. George Washington University, Washington, D.C.
1978	M.D. George Washington University, Washington, D.C.

**Work Experience**

1969-1970	Research (Student) at the National Institutes for Health
1970-1971	NIH Traineeship at Columbia University, Department of Human Genetics and Development, N.Y.C.
1978-1979	Intern and Fellow, Department of Obstetrics and Gynecology, The Johns Hopkins Hospital, Baltimore, Maryland
1979-1982	Assistant Professor, Department of Gynecology and Obstetrics, The Johns Hopkins School of Medicine, Baltimore, Maryland
1980-1982	Guest Worker Laboratory of General and Comparative Biochemistry, NIMH, NIH
1981-1984	Assistant Research Prof. Psych. Department U.S.U.H.S., Bethesda, Maryland
1988-1994	Director of Genetics of Maryland Medical Laboratory, Inc., Baltimore, Maryland





1989-1994 Member of the Substance Abuse and Doping Committee and the Sports Medicine and Science Committee of the U.S. Bobsled and Skeleton Federation (Olympic Committee)

**State Licensors:**

Maryland, September 1979-present;  
Virginia, October 1992-present

**Board Certification:**

American Board of Medical Genetics, 1987  
Associate Member of the American College of Medical Genetics, 1993  
Board Certified by the American Board of Forensic Examiners 1996  
Diplomate of the American Board of Forensic Medicine 1996

**Other Positions:**

1980-present Co-director of Genetic Consultants of Maryland, Rockville, Maryland

1980-present Laboratory Directory Molecular Medicine, Maryland

1981-present Director of Institute of Immuno-Oncology and Genetics, Maryland

1986-present President of Genetic Counseling and Research, Inc., T/A The Genetic Center Baltimore, Maryland

1997-present President of Genetic Counseling and Research, Inc., T/A The Ultrasound Institute of Baltimore, Maryland

1997-present President of The Genetic Centers of America

2001 Host of one hour weekly medical talk show "The Dr. Mark Geier Show" on KFNX in Phoenix, Arizona, WALE in Provident, Rhode Island and on the World Wide Web.

2001 Clinical and Experimental Rheumatology Journal Peer-Reviewer

2002 Environmental Health Perspectives Journal Peer-Reviewer

2002 Expert Reviewer of Vaccines Journal Peer-Reviewer

**Professional Societies:**

Sigma Psi

American Association for Advancement

National Board of Medical Examiners, Diplomat

American Society of Human Genetics

Montgomery County Medical Society

American Fertility Society

In Who's Who in America 1992-present

**Publications:**

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2. Merrill, C.R., Geier, M.R. Petricciani, J. "Bacterial virus gene expression in human cells." Nature 233: 398-400 (1971).
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9. Geier, M.R. "The Effect of Prokaryotic Genes in Eukaryotes." Ph.D. Dissertation submitted to The George Washington University 1973.
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Journal of Medicine 289: 755 (1973).

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